

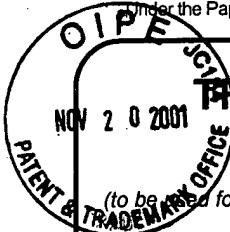
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**TRANSMITTAL  
FORM**

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission

1

Application Number	09/978,112
Filing Date	October 15, 2001
First Named Inventor	Rivera, Roberto L.
Group Art Unit	Not yet assigned
Examiner Name	Not yet assigned

Attorney Docket Number

019664-000410US

**ENCLOSURES (check all that apply)**

<input type="checkbox"/> Fee Transmittal Form	<input type="checkbox"/> Assignment Papers (for an Application)	<input type="checkbox"/> After Allowance Communication to Group
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<input type="checkbox"/> Affidavits/declaration(s)	<input type="checkbox"/> Petition to Convert to a Provisional Application	<input type="checkbox"/> Status Letter
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<input type="checkbox"/> Response to Missing Parts/ Incomplete Application		Remarks
<input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53		The Commissioner is authorized to charge any additional fees to Deposit Account 20-1430.

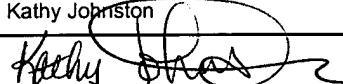
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Firm and Individual name	Townsend and Townsend and Crew LLP Hugh Wang	
Signature		
Date	November 14, 2001	

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**PATENT**  
Attorney Docket No.: 019664-000410US

Assistant Commissioner for Patents  
Washington, D.C. 20231

On November 14, 2001

TOWNSEND and TOWNSEND and CREW LLP

By 



**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of:

Roberto L. Rivera

Application No.: 09/978,112

Filed: October 15, 2001

For: DELIVERY SYSTEM TO  
MODULATE IMMUNE RESPONSE

Examiner: Not yet assigned

Art Unit: Not yet assigned

**INFORMATION DISCLOSURE  
STATEMENT UNDER 37 CFR §1.97 and  
§1.98**

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

The references cited on attached form PTO/SB/08A and PTO/SB/08B are being called to the attention of the Examiner. Copies of the references are enclosed. It is respectfully requested that the cited references be expressly considered during the prosecution of this application, and the references be made of record therein and appear among the "references cited" on any patent to issue therefrom.

As provided for by 37 CFR 1.97(g) and (h), no inference should be made that the information and references cited are prior art merely because they are in this statement and no

representation is being made that a search has been conducted or that this statement encompasses all the possible relevant information.

Applicant believes that no fee is required for submission of this statement, since it is being submitted prior to the first Office Action. However, if a fee is required, the Commissioner is authorized to deduct such fee from the undersigned's Deposit Account No. 20-1430. Please deduct any additional fees from, or credit any overpayment to, the above-noted Deposit Account.

Respectfully submitted,



Hugh Wang  
Reg. No. 47,163

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Substitute for form 1449A/PTO

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 2

Complete if Known

Application Number	09/978,112
Filing Date	October 15, 2001
First Named Inventor	Rivera, Roberto L.
Group Art Unit	Not yet assigned
Examiner Name	Not yet assigned
Attorney Docket Number	019664-000410US

### U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
	AA	5,417,986		R. Reid et al.	23 May 1995	
	AB	5,591,433		Michael et al.	07 Jan 1997	
	AC	5,629,001		J. Michael et al.	13 May 1997	

### FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
	AD	EP	0 603 992 A1			29 Jun 1994		Yes
	AE	FR	FR 2723849 A			01 Mar 1996		Abstract Only
	AF	JP	JP 1287032 A			17 Nov 1989		Abstract Only
	AG	PCT	WO9423738			27 Oct 1994		No

Examiner Signature	Date Considered
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<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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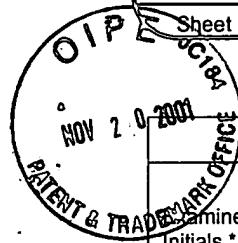
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of 2

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Examiner Name	Not yet assigned
Attorney Docket Number	019664-000410US



### OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	AH	DISIS, et al., <u>High-Titer HER-s/neu Protein-Specific Antibody Can Be Detected in Patients With Early-Stage Breast Cancer</u> , Journal of Clinical Oncology, Vol. 15, No. 11 (November), 1997, p. 3363-3367.	
	AI	DISIS, et al., <u>Peptide-Based, but Not Whole Protein, Vaccines Elicit Immunity to HER-s/neu, an Oncogenic Self-Protein</u> , Journal of Immunology, 1996, p. 3151-3158.	
	AJ	IRACHE, et al., <u>Bioadhesion of Lectin-Latex Conjugates to Rat Intestinal Mucosa</u> , Pharmaceutical Research, Vol. 13, No. 11, 1996, p. 1716-1719.	
	AK	KOTZE, et al., <u>N-Trimethyl Chitosan Chloride as a Potential Absorption Enhancer Across Mucosal Surfaces: In Vitro Evaluation in Intestinal Epithelial Cells (Caco-2)</u> , Pharmaceutical Research, Vol. 14, No. 9, 1997, p. 1197-1202.	
	AL	MALOY, et al., <u>Induction of mucosal and systemic immune responses by immunization with ovalbumin entrapped in poly(lactide-co-glycolide) microparticles</u> , Immunology, 1994, 81, p. 661-667	
	AM	MOWAT, et al., <u>Immune-stimulating complexes containing Quil A and protein antigen prime class I MHC-restricted T lymphocytes in vivo and are immunogenic by the oral route</u> , Immunology, 1991, 72, p. 317-322.	
	AN	REID, GEORGE, <u>Soluble proteins incorporate into ISCOMs after covalent attachment of fatty acid</u> , Vaccine, 1992, Vol. 10, No. 99, p. 597-602.	
	AO	ROBBINS-ROTH, CYNTHIA, <u>Cancer Vaccines: Are we finally on the right track?</u> , Bioventure View, Vol. 12, No. 18, 1997, p.1, 2, 4-10.	
	AP	ROCK, et al., <u>Analysis of the Role of MHC Class II Presentation in the Stimulation of Cytotoxic T Lymphocytes by Antigens Targeted into the Exogenous Antigen-MHC Class I Presentation Pathway</u> , Journal of Immunology, 1996, p. 3721-3726, American Association of Immunologists.	
	AQ	ROCK, et al., <u>Inhibition of Class I and Class II MHC-Restricted Antigen Presentation by Cytotoxic T Lymphocytes Specific for an Exogenous Antigen</u> , Journal of Immunology, 1992, Vol. 148, p. 3028-3033.	
	AR	SCHIPPER, et al., <u>Chitosans as Absorption Enhancers for Poorly Absorbable Drugs 2: Mechanism of Absorption Enhancement</u> , Pharmaceutical Research, Vol. 14, No. 7, 1997, p. 923-929.	
	AS	VIDARD, et al., <u>Analysis of MHC Class II Presentation of Particulate Antigens by B Lymphocytes</u> , Journal of Immunology, 1996, p. 2809-2818, American Association of Immunologists.	

Examiner Signature	Date Considered
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